K021265

AUG 3 0 2002

Premarket Notification 510(k) Summary
As required by section 807.92
Datex-Ohmeda HMEF 500

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

Datex-Ohmeda
86 Pilgrim Road
Needham, MA 02492 USA
Tel: 781-449-8685
Fax: 781-433-1344

NAME OF CONTACT:

Mr. Joel Kent

DATE:

August 29, 2002

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

Datex-Ohmeda HMEF 500

COMMON NAME:

Disposable Heat and Moisture Exchanger and Bacteria/Viral Filter

CLASSIFICATION NAME:

The following Class II classification appears applicable:

CAH Breathing Circuit Bacterial Filter 868.5260

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The Datex-Ohmeda HMEF500 is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda HMEF1000 (K964204) and predicate EMS HEPA Filter and Hepa Filter/HME (K013089).

DEVICE DESCRIPTION as required by 807.92(a)(4)

The intended use for the modified device is the same as the predicate.

Indication for use: The HMEF500 is a disposable single–use device indicated for patients who require humidification during the delivery of ventilator gases and provide filtration for reducing possible cross contamination between patient and equipment. The HMEF 500 is for use in hospital, ICU, anesthesia, respiratory therapy, during transport and with resuscitators. The device is indicated for use by qualified medical personnel only.

There has been no change to the fundamental scientific technology from the predicate.

The device description of the Datex-Ohmeda HMEF500 is as follows:
The HMEF 500 incorporates a hygroscopically treated HME media and electrostatic filter media into a housing made of translucent plastic.
Diameter: 45 mm
Length: 74 mm
Material:
HMEF 500
- Housing: PP Polypropylene
- HME-element: PU Polyurethane impregnated with calcium chloride CaCl2
- Filter: PP and acrylic fibers
Filtration efficiency:
- Filtration efficiency viral 99.9 %
- Filtration efficiency bacterial 99.9999999 %
The HMEF 500 is for use in adult and pediatric patients in the hospital, ICU, anesthesia, respiratory therapy, during transport and with resuscitators.
It incorporates standard fittings for-
15 mm ID x 22 mm OD fitting to connect to the endotracheal tube or face mask
15 mmOD x 22 mm ID fitting to connect to the breathing circuit y-piece
A gas sampling port – female luer port with cap to allow sampling of expired CO2-gases

The modifications to the device are:
The Datex-Ohmeda HMEF500 has the following differences when compared to the Datex-Ohmeda HMEF1000 predicate device:
The devices differ in size, weight, diameter, dead space
The devices differ in Moisture output @ 500 ml, Moisture loss, Breathing resistance @30 litre/minute and Tidal Volume
The devices differ in labeled shelf life
- Filtration efficiency against bacteria: HMEF 1000 99,999999%, HMEF 500 99,9999999%
- Filtration efficiency against virus: HMEF 1000 99,99%, HMEF 500 99,9%

The main differences between the Datex-Ohmeda HMEF500 and Datex-Ohmeda HMEF1000 (K964204) are due to fact that the size of the Datex-Ohmeda HMEF500 is smaller than the Datex-Ohmeda HMEF1000 (K964204). This makes the HMEF500 suitable for use in patients with lower tidal volumes.

The HMEF 500 has a lower breathing resistance at 60 lpm than the predicate EMS HEPA Filter and Hepa Filter/HME (K013089). The HMEF 500 resistance at 60 lpm is 3.3 cm H_2O compared to is 3.4 cm H_2O for the predicate EMS HEPA Filter and Hepa Filter/HME (K013089).

INTENDED USE as required by 807.92(a)(5)

Indication for use: The HMEF500 is a disposable single–use device indicated for patients who require humidification during the delivery of ventilator gases and provide filtration for reducing possible cross contamination between patient and equipment. The HMEF 500 is for use in hospital, ICU, anesthesia, respiratory therapy, during transport and with resuscitators. The device can be used on adult and pediatric patients. The device is indicated for use by qualified medical personnel only.

SUMMARY OF TECHNOLOGICAL CHARACTERITICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The Datex-Ohmeda HMEF500 is substantially equivalent in safety and effectiveness to the legally marketed (predicate) EMS HEPA Filter and Hepa Filter/HME (K013089) and Datex-Ohmeda HMEF1000 (K964204).
The Datex-Ohmeda HMEF500 has the following similarities to the EMS HEPA Filter and Hepa Filter/HME and Datex-Ohmeda HMEF1000 predicate devices:
-have basically the same indicated use
-Both the HMEF 500 and predicate EMS HEPA Filter and Hepa Filter/HME, HMEF 1000 give efficient protection against transfer of bacteria / viruses between patients, personnel and equipment

The Datex-Ohmeda HMEF500 has the following differences when compared to the EMS HEPA Filter and Hepa Filter/HME and Datex-Ohmeda HMEF1000 predicate devices:
-The devices differ in size, weight, diameter, dead space
-The devices differ in Moisture output @ 500, Breathing resistance @30 litre/minute, @60 litre/minute and Tidal Volume
-Filtration efficiency against bacteria: HMEF 1000 99.999999 %, HMEF 500 99.9999999 % and EMS HEPA Filter and Hepa Filter/HME 99.9999%.
-Filtration efficiency against virus: HMEF 1000 99.99%, HMEF 500 99.9% and EMS HEPA Filter and Hepa Filter/HME 99.9999%

The main differences between the Datex-Ohmeda HMEF500 and Datex-Ohmeda HMEF1000 (K964204) are due to fact that the size of the Datex-Ohmeda HMEF500 is smaller than the Datex-Ohmeda HMEF1000 (K964204). This makes the HMEF500 suitable for use in patients with lower tidal volumes.

The HMEF 500 has a lower breathing resistance at 60 lpm than the predicate EMS HEPA Filter and Hepa Filter/HME (K013089). The HMEF 500 resistance at 60 lpm is 3.3 cm H_2O compared to is 3.4 cm H_2O for the predicate EMS HEPA Filter and Hepa Filter/HME (K013089).

In summary, the Datex-Ohmeda HMEF500, described in this submission is substantially equivalent to the predicate devices.

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

The Datex-Ohmeda HMEF 500 complies with the safety standards below and is therefore safe and effective for the intended use. The device has been thoroughly tested through validation and verification of specifications. Verification of compliance with the following mandatory and voluntary standards has been made:

- ISO 9360:1992
- ISO 5356-1:1996
- ISO 594-1:1986"
- ISO 594-2:1998
- EN 980:1996
- EN 1041:1998
- EN 13014
- ASTM F 1054-8721

Conclusion:
The summary above shows that there are no new questions of safety and effectiveness for the Datex-Ohmeda HMEF 500 as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 0 2002

Mr. Joel C. Kent
Manager, Quality and Regulatory Affairs
Datex-Ohmeda
86 Pilgrim Road
Needham, Massachusetts 02492

Re: K021265
Trade/Device Name: Datex-Ohmeda HMEF500
Regulation Number: 868.5260
Regulation Name: Breathing Circuit Bacterial Filter
Regulatory Class: II
Product Code: CAH
Dated: July 31, 2002
Received: August 1, 2002

Dear Mr. Kent:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K021265

Device Name: Datex-Ohmeda HMEF 500

The HMEF500 is a disposable single-use device indicated for patients who require humidification during the delivery of ventilator gases and provide filtration for reducing possible cross contamination between patient and equipment. The HMEF 500 is for use in hospital, ICU, anesthesia, respiratory therapy, during transport and with resuscitators. The device can be used on adult and pediatric patients. The device is indicated for use by qualified medical personnel only.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K021265